UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: FOSAMAX (ALENDRONATE SODIUM) PRODUCTS LIABILITY LITIGATION	
BERNADETTE GLYNN and RICHARD GLYNN,	Civil Action No. 11-5304, 08-08
Plaintiffs,	OPINION
v.	
MERCK SHARP & DOHME CORP,	
Defendant.	

PISANO, District Judge

Plaintiffs Bernadette Glynn and Richard Glynn ("Plaintiffs") brought this lawsuit against Defendant Merck, Sharp, & Dohme Corp. ("Defendant"), the manufacturer of Fosamax, which is a drug approved by the United States Food and Drug Administration ("FDA") for the treatment and prevention of osteoporosis. This matter is part of the multi-district litigation concerning Fosamax and involves allegations that Fosamax causes atypical femur fractures ("AFFs[1]"), it caused Plaintiff Mrs. Glynn's femur fracture, and Defendant failed to warn physicians about Fosamax and AFFs. Presently before the Court is Defendant's Motion for Summary Judgment on Plaintiffs' failure to warn, breach of implied warranty of fitness for a particular purpose, and New York General Business Law claims as well as on Plaintiffs' request for punitive damages

[1] The abbreviation of atypical femur fracture (singular) is "AFF."

[docket # 24].[2] This Court heard oral argument on the Motion on March 8, 2013 and April 2, 2013. *See* Fed. R. Civ. P. 78. For the reasons discussed below, this Court will deny the Motion as to the failure to warn, breach of implied warranty of fitness for a particular purpose, and punitive damages claims and grant the Motion as to the New York General Business Law claims.

I. BACKGROUND

A. Fosamax and Label Change

In September 2005, the FDA approved Fosamax for the treatment of osteoporosis in postmenopausal women, and in April 2007, the FDA approved Fosamax for the prevention of osteoporosis in postmenopausal women. Since this time, Fosamax has remained FDA approved for the treatment and prevention of postmenopausal osteoporosis.

On June 13, 2008, a representative from the FDA e-mailed Defendant, stating that the FDA is "aware of reports regarding the occurrence of subtrochanteric hip fractures in patients using bisphosphonates" and is "concerned about this developing safety signal" [docket # 101, Declaration of James E. Cecchi in Support of the Memorandum of Law in Opposition to Defendant's Motion for Summary Judgment ("Cecchi Dec."), Ex. 82]. The FDA requested any investigations Defendant conducted "regarding the occurrence of atypical fractures with bisphosphonate use as well as any investigational plans" and "all hip and femoral fracture case reports" Defendant received. *Id.*

On September 15, 2008, Defendant submitted a Prior Approval Supplement to the FDA, proposing "to add language to both the Precaution and Adverse Reaction/Post-Marketing

[2] Defendant's initially moved for Summary Judgment on several more causes of action [*see* docket # 24], but Plaintiffs decided not to pursue certain claims and only the failure to warn, breach of implied warranty of fitness for a particular purpose, New York General Business Law, and punitive damages claims remain [*see* docket # 95, p. 1, n. 1].

Experience section[s] of the label to describe low-energy" femoral fractures of the subtrochanteric region [docket # 27, Declaration of Karen A. Confoy in Support of Defendant's Motion for Summary Judgment ("Confoy Dec."), Ex. 8]. Defendant stated that "[i]t is not possible with the present data to establish whether treatment with" Fosamax increases the risk of these fractures, but because there is a temporal association between these fractures and Fosamax, Defendant thought that it was "important to include an appropriate statement about them in the product label." *Id.* On April 15, 2009, an FDA representative e-mailed Defendant and stated that the proposed label change would be approved for inclusion in the Postmarketing Adverse events section of the label but not in the Precaution section of the label [docket # 101, Cecchi Dec., Ex. 83]. The FDA representative informed Defendant that it would work with Defendant to decide on language to include in the Warnings and Precautions section of the label. *Id.* On May 22, 2009, the FDA formally responded to Defendant's proposed label change, recommending that it add "low energy femoral shaft and subtrochanteric fractures" to the Adverse Reactions, Post-Marketing Experiences subsection of the label; however, the FDA did not approve the inclusion of AFFs in the Precautions section of the label because Defendant's "justification for the proposed PRECAUTIONS section language is inadequate" [docket # 26, Confoy Dec., Ex. 11].

In October 2010, the FDA issued a Drug Safety Communication, warning the public about the risk of AFFs in patients who take bisphosphonates, such as Fosamax, for the prevention and treatment of osteoporosis [docket # 26, Confoy Dec., Ex. 15]. The FDA noted that it would require all bisphosphonate manufacturers to add this information to the Warning and Precautions section of the drug labels and require a new Limitations of Use statement in the Indications and Usage section of the labels because "these atypical fractures may be related to

long-term . . . bisphosphonate use." *Id.* The current prescribing information for Fosamax includes the following information: "Atypical, low-energy, or low trauma fractures of the femoral shaft have been reported in bisphosphonate-treated patients. . . . Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with bisphosphonates. Atypical femur fractures[3] most commonly occur with minimal or no trauma to the affected area" [docket # 26, Confoy Dec., Ex. 20].

B. Mrs. Glynn's Treatment

In 2002, Mrs. Glynn's primary care doctor, Dr. Murat Acemoglu ("Dr. Acemoglu"), requested that she undergo a DEXA scan to measure her bone mineral density. After reviewing the DEXA scan results, Dr. Acemoglu diagnosed her with "osteopenia – osteoporosis" [docket # 27, Confoy Dec., Ex. 27 & 28]. Dr. Acemoglu prescribed Fosamax to Mrs. Glynn but did not give her anything to read about Fosamax at that time [docket # 26, Confoy Dec., Mrs. Glynn Deposition ("Dep."), at 175:25-176:1; docket # 100, Cecchi Dec., Ex. 58]. Mrs. Glynn testified that Dr. Acemoglu told her to take Fosamax once a week, to drink a lot of water when taking it, and not to lie down after taking the pill [docket # 26, Confoy Dec., Ex. 26, Mrs. Glynn Dep., at 175:10-13, 176:8-13]. She read the prescribing information that came with her prescription of

[3] In 2010, the American Society for Bone and Mineral Research ("ASBMR") defined AFF by listing its Major Features, which are required to satisfy the definition of AFF, and Minor Features, which may be associated with AFFs but are not required characteristics of them [docket # 26, Confoy Dec., Ex. 13]. The Major Features of an AFF are: (1) that it is "located anywhere along the femur from the distal to the lesser trochanter to just proximal to the supracondylar flare"; (2) "associated with no trauma or minimal trauma, as in a fall from a standing height or less"; (3) transverse or short oblique configuration; (4) noncomminuted; and (5) complete fractures extend through both cortices and may be associated with a medial spike, incomplete fractures involve only the lateral cortex. *Id.* The Minor Features of an AFF are: (1) localized periosteal reaction of the lateral cortex; (2) generalized increase in cortical thickness of the diaphysis; (3) prodromal symptoms such as dull or aching pain in the groin or thigh; (4) bilateral fractures and symptoms; (5) delayed healing; (6) comorbid conditions (e.g., vitamin D deficiency, rheumatoid arthritis, hyposphosphotasia); and (7) use of pharmaceutical agents (e.g., bisphosphonates, glucocorticoids, and proton pump inhibitors). *Id.*

Fosamax, although she does not remember "word for word what it said" except that one should not lie down after taking the drug. *Id.* at 176:14-177:2. Mrs. Glynn did not see any advertising for Fosamax. In July 2005, Dr. Acemoglu passed away.

After Dr. Acemoglu passed away, Mrs. Glynn received primary care treatment from Drs. Jessica Berman ("Dr. Berman") and Adrian Karatnycky ("Dr. Karatnycky") [docket #101, Cecchi Dec., Ex. 69, Dr. Karatnycky's Deposition ("Dr. Karatnycky Dep."), at 97:9-13), and Nurse Darlene Hoffman ("Nurse Hoffman") at Troy Internal Medicine. Additionally, since 1997, Dr. Laura Costello ("Dr. Costello"), an OB/GYN, treated her. Drs. Berman, Costello, and Karatnycky, and Nurse Hoffman each prescribed Mrs. Glynn Fosamax, and she took the drug or a generic version of it until April 2009, when she fractured her femur [docket # 100, Cecchi Dec., Ex. 61 & 62].

Dr. Berman treated Mrs. Glynn once, on August 31, 2005, and she refilled Mrs. Glynn's Fosamax prescription at that time [docket # 100, Cecchi Dec., Ex. 60, Dr. Berman's Deposition ("Berman Dep."), at 6:7-12, 9:1-2, 68:19-69:9]. Dr. Berman testified that her decision to refill Mrs. Glynn's Fosamax prescription was appropriate [docket # 26, Ex. 31, Confoy Dec., Berman Dep., 87:11-14]. She testified that "had [she] known in 2005 when [she] continued M[r]s. Glynn on Fosamax what [she] know[s] today about femur fractures, that information wouldn't have changed [her] decision to continue M[r]s. Glynn on Fosamax." *Id.* at 87:18-88:2. Although Dr. Berman continues to prescribe the generic, alendronate, to patients because "any risks are outweighed by the benefit of reducing a fracture by 50 percent," *id.* at 87:4-10, she no longer prescribes biphosphonates to patients to prevent osteoporosis; she made this change "between three to five years ago" [docket # 100, Cecchi Dec., Ex. 60, Berman Dep., at 36:4-12]. In addition, Dr. Berman now suggests a drug holiday to her patients after five years. *Id.* at 50:2-4.

Dr. Costello wrote Mrs. Glynn prescriptions for Fosamax and the generic, alendronate, in 2005, 2006, 2007, and 2009 [docket # 100, Cecchi Dec., Ex. 55, Dr. Costello's Deposition ("Costello Dep."), at 171:3-12; Ex. 60 & 61]. During this time, Dr. Costello still considered Mrs. Glynn's primary care physician to be managing her bones, but Dr. Costello would write the Fosamax prescriptions as a matter of convenience [docket # 100, Cecchi Dec., Ex. 55, Costello Dep., at 108:3-17]. Prior to writing a prescription for Fosamax, Dr. Costello evaluated Mrs. Glynn to determine whether the benefits of Fosamax outweighed the risks for her, and Dr. Costello found that they did. *Id.* at 97:6-21. Dr. Costello testified that she undertook this benefits and risk analysis several times when refilling Mrs. Glynn's Fosamax prescription, *see id.* at 99:21-100:1; 103:12-19, but at one point in her testimony, Dr. Costello states that she "can't remember" going over the risk and benefit analysis of Fosamax with Mrs. Glynn, although it was something she typically did. *Id.* at 163:4-16.

Dr. Costello further testified that she still prescribes Fosamax to her patients for the treatment and prevention of osteoporosis. *Id.* at 50:14-24; 130:14-21. She continues to prescribe Fosamax because she "believe[s] that the slight risk of an atypical femur fracture is outweighed by [the] overall benefit of reducing all the other types of fractures." *Id.* at 131:15-24; *see also id.* at 53:16-54:1. She does not specifically tell her patients the risk of AFF, however, because they are a "very low risk." *Id.* at 61:6-18. Yet, Dr. Costello then stated that she does discuss AFFs "if a woman has been on Fosamax for [a] period of time" because they are a "serious adverse effect" and "it's something important for them to know so they can make an informed decision." *Id.* at 178:1-18. She testified that she relies on the FDA's approved label of a drug when deciding whether to prescribe the drug to her patients and she familiarizes herself with the risk information contained in the label; she also tries to keep up with the FDA's changes to the label.

Id. at 30:17-31:9; 14-:8-24. Dr. Costello's prescribing practices regarding Fosamax have changed; in fact, her prescriptions decreased, and she is prescribing "calcium and vitamin D more than Fosamax." *Id.* at 51:1-7. She explained that she changed her behavior because "atypical fractures . . . raised a flag." *Id.* at 52:7-11.

It appears that Dr. Karatnycky prescribed Fosamax to Mrs. Glynn in 2006 and wrote three refill prescriptions for Fosamax in 2007 [docket # 101, Cecchi Dec., Ex. 61; Ex. 69, Dr. Karatnycky's Deposition ("Karatnycky Dep."), at 62:24-63:9; Ex. 70]. In 2006, a DEXA bone scan revealed that Mrs. Glynn's bone mineral density improved. Based on these results, he opined that "Fosamax was having a beneficial effect for Mrs. Glynn in terms of increasing her bone mass" [docket # 26, Confoy Dec., Ex. 32, Karatnycky Dep., at 89:2-21]. He finds Fosamax effective for treatment of patients with osteoporosis, and he "assume[s] . . . that . . . improving the bone density with . . . Fosamax would naturally reduce the risk of osteoporotic fractures." *Id.* at 59:14-60:18. Dr. Karatnycky testified that if there "was a warning saying that Fosamax was associated with femur fractures," then that "would have possibly triggered a communication" with Mrs. Glynn, especially if he had seen her for an office visit [docket # 101, Cecchi Dec., Ex. 69, Karatnycky Dep., at 206:5-18]. He states that if the information was in the label's warning section, he would have "passed that [information] along" and "possibly even stopped the Fosamax at that point." *Id.* at 82:15-83:8; 207: 2-5. He relies on the information in the label to inform him about the risk and benefits of a drug. *Id.* at 18:15-20.

Dr. Karatnycky changed his prescribing habits in 2011 and now has a "conversation with . . . patients after five years or three to five years about whether they should take the medication." *Id.* at 184:20-185:6. This change in prescribing habits was based on the published data on the "increased risk of atypical fractures." *Id.* at 185:13-186:4. Dr. Karatnycky testified that he

would take patients off Fosamax if they are "no longer severely osteopenic" but will continue the drug if the patient continues to be osteopenic. *Id.* at 186:16-187:10.

Nurse Hoffman wrote Fosamax or alendronate sodium prescriptions for Mrs. Glynn beginning in 2008. She testified that her decision to continue Mrs. Glynn on Fosamax in 2008 was appropriate [docket # 101, Cecchi Dec., Ex. 71, Nurse Hoffman's Deposition ("Hoffman Dep.") at 122:16-19]. Nurse Hoffman has found Fosamax to be effective for the treatment and prevention of osteoporosis, and she relies on a drug's labeling "in considering whether to prescribe medication for a patient." *Id.* at 39:11-14; 70:8-14. Additionally, she testified that "had [she] known then what [she] know[s] today about this issue of fracture," she would have probably had "a different discussion with" Mrs. Glynn regarding Fosamax. *Id.* at 122:20-123:4. A couple of years ago, Nurse Hoffman began recommending that patients consider going off Fosamax after five years. *Id.* at 76:12-17.

C. Mrs. Glynn's Femur Fracture

On April 17, 2009, Mrs. Glynn sustained a fracture to her right femur. Final Pretrial Order ¶ 3. An ambulance took Mrs. Glynn to St. Mary's Hospital in Troy, New York where Dr. Frederick Fletcher operated on her [docket # 26, Confoy Dec., Ex. 41, Dr. Fletcher's Deposition at 48]. About a year after the fracture, Dr. Fletcher examined Mrs. Glynn and said the fracture "healed beautifully," although he noted that she was still complaining of some pain. *Id.* at 80:1-19. In August 2009, approximately four months after her surgery, Mrs. Glynn began biking and swimming again. [docket # 27, Confoy Dec., Ex. 42].

D. Plaintiffs' Complaint

On September 15, 2011, Mrs. Glynn directly filed a Complaint in this Court against Defendant, alleging causes of action for: (1) failure to warn; (2) defective design; (3) negligence; (4) negligent misrepresentation; (5) breach of express warranty; (6) breach of implied warranty of fitness for a particular purpose; (7) breach of implied warranty of merchantability; (8) violation of the Consumer Fraud Act, N.J.S.A. 56:8-2 et seq.; (9) violations of the New York General Business Law (N.Y. Gen. Bus. Law §§ 349 et seq. and 350 et seq.); (10) unjust enrichment; (11) punitive damages pursuant to the N.J. Product Liability Act (N.J.S.A. 2A:58C-1 et seq.) and the N.J. Punitive Damages Act (N.J.S.A. 2A:15-5.10, et seq.); and (12) loss of consortium on behalf of Plaintiff Richard Glynn [docket # 1]. Defendant moved for summary judgment on January 15, 2013 [docket #24]. Subsequently, Plaintiffs decided to pursue only the following claims: (1) failure to warn; (2) breach of the implied warranty of fitness for a particular purpose; (3) violations of the New York General Business Law; and (4) punitive damages; therefore, Defendant's Motion for Summary Judgment applies to these claims only.

II. DISCUSSION

A. Summary Judgment Standard

To prevail on a motion for summary judgment, the moving party must establish "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a genuine dispute of material fact exists, the court must view the facts in the light most favorable to the nonmoving party and extend all reasonable inferences to that party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*,

475 U.S. 574, 587 (1986); *Stephens v. Kerrigan*, 122 F.3d 171, 176–77 (3d Cir. 1997). The Court is not required to "weigh the evidence and determine the truth of the matter" but instead need only determine whether a genuine issue necessitates a trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248.

On a summary judgment motion, the moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party makes this showing, the burden shifts to the nonmoving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. The nonmoving party must then offer admissible evidence that establishes a genuine issue of material fact, *id.*, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co.*, 475 U.S. at 586.

B. Failure to Warn[4]

Defendant argues that summary judgment must be granted because Plaintiffs are unable to establish the proximate cause element of failure to warn since none of Mrs. Glynn's prescribing doctors testified that a different warning would have changed their decision to prescribe Fosamax. Plaintiffs, however, assert that summary judgment should be denied because material issues of fact exist regarding whether Defendant's failure to warn Mrs. Glynn's doctors about AFFs was a proximate cause of her injuries. Plaintiffs contend that proximate cause requires them to show that an appropriate warning would have changed the manner in which the drug was prescribed and not that it would have changed a doctor's decision to prescribe

[4] The parties agree that New York law governs Plaintiffs' substantive claims. *See* Final Pretrial Order at 32 [docket # 150].

Fosamax. For example, Plaintiffs claim that prescribing the drug in a different manner includes the doctor passing on new warnings, having a detailed discussion with the patient, recommending a drug holiday, and engaging in an individual patient analysis. Moreover, Plaintiffs argue that New York's heeding presumption applies, meaning if a warning was provided to the prescribing doctor, he or she would have heeded that warning. Lastly, Plaintiffs point out that to the extent her prescribing doctors provided conflicting testimony, the testimony should be assessed by a trier of fact. Defendants replied, arguing that Plaintiffs cannot prove failure to warn where a different warning would not have changed Mrs. Glynn's doctors' prescribing decisions. Defendants point out that none of Mrs. Glynn's doctors testified that they would not have prescribed Fosamax to Mrs. Glynn if the label contained its current warnings.

"Under New York law, a failure to warn claimant must show (1) that a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known and (3) that failure to do so was the proximate cause of harm." *In re Fosamax Products Liab. Litig. (Scheinberg v. Merck & Co.)*, 2013 WL 76140, *3 (S.D.N.Y. Jan. 7, 2013). To "establish proximate causation in a failure to warn claim resulting from a pharmaceutical product, a plaintiff must show that an appropriate warning would have affected the course of treatment of the plaintiff's physician." *Id.* at *4. Stated differently, the plaintiff must show that "had a different, more accurate warning[] been given, his physician would not have prescribed the drug in the same manner." *Alston v. Caraco Pharmaceutical, Inc.*, 670 F. Supp. 2d 279, 285 (S.D.N.Y. 2009). New York's learned intermediary doctrine provides that "the duty to warn is met by providing information to the prescribing physician, not to the patient directly." *Id.* at 284; *see also Mulhall v. Hannafin*, 45 A.D.3d 55, 58, 841 N.Y.S.2d 282 (N.Y. App. Div. 2007).

Here, the Court has reviewed the testimony of Drs. Berman, Costello, Karatnycky, and Nurse Hoffman and finds conflicting testimony regarding whether an appropriate Fosamax warning would have affected the course of treatment of Mrs. Glynn's prescribing physicians or changed the manner in which they prescribed the drug to her. Although Drs. Berman, Costello, Karatnycky, and Nurse Hoffman have testified that they changed the manner in which they prescribe Fosamax, they have not definitively stated, with the exception of Dr. Berman who saw Mrs. Glynn once, whether an appropriate warning would have affected the doctors' prescribing practices regarding Mrs. Glynn. *See* docket # 26, Confoy Dec., Ex. 31, Berman Dep., at 87:18-88:2; docket # 100, Cecchi Dec., Ex. 55, Costello Dep., at 52:7-11, 132:1-10; docket # 100, Cecchi Dec., Ex. 60, Berman Dep., at 36:4-12, 50:2-4; docket # 101, Cecchi Dec., Ex. 69, Karatnycky Dep., at 82:15-83:8, 184:20-185:6, 206:5-18, 207:2-5; docket # 101, Cecchi Dep., Ex. 71, Hoffman Dep., at 76:12-17, 122:16-123:4. As a result, "[i]t is for the jury to decide which of [the doctors' statements] to credit." *In re Fosamax Products Liab. Litig.*, 2013 WL 76140, at *4. Therefore, this Court will deny Defendant's Motion for Summary Judgment without prejudice as to failure to warn.

C. Breach of Implied Warranty of Fitness for a Particular Purpose

Defendant argues that summary judgment should be granted because it did not breach an implied warranty of fitness for a particular purpose. Defendant asserts that Fosamax is intended and FDA approved for the particular purpose of treating and preventing osteoporosis, and there is no evidence that its statements about Fosamax's efficacy, which are approved by the FDA, were false, misleading, and inaccurate. In addition, Defendant contends that it never warranted that Fosamax was without risk to a person's body and health and notes that prescription medications have known risks.

Plaintiffs argue that Mrs. Glynn and her prescribing doctors relied on Defendant's representations that Fosamax was an appropriate treatment for her osteopenia, and they expected that Fosamax would improve her bone density and prevent fractures; instead, the drug allegedly caused Mrs. Glynn's AFF.

Defendants replied, arguing that using Fosamax for the purpose of treating or preventing osteoporosis, its FDA approved use, is not a particular purpose, but the "normal, regular, expected purpose" of the drug (Drb7) [5]. Defendants contend that if using Fosamax to treat or prevent osteoporosis is a particular purpose, then Fosamax is fit for that purpose because of its continued FDA approval. Lastly, Defendant argues that this claim stems from Mrs. Glynn's misunderstanding of what the Fosamax label said regarding the drug's benefits; Defendant never communicated to Mrs. Glynn's "doctors that Fosamax prevents *all* fractures at *all* sites of the body in *all* patient populations (both osteoporotic and osteopenic)" (Drb7).

To establish a breach of an implied warranty of fitness for a particular purpose, "the buyer must establish that the seller had reason to know, at the time of contracting, the buyer's particular purpose for which the goods are required and that the buyer was justifiably relying upon the seller's skill and judgment to select and furnish suitable goods, and that the buyer did in fact rely on that skill . . . ." *Saratoga Spa & Bath, Inc. v. Beech Sys. Corp.*, 656 N.Y.S.2d 787, 790 (N.Y. App. Div. 1997). Thus, the "existence of this warranty . . . depends in part upon the comparative knowledge and skill of the parties." *Id.*

Here, the Court finds that material issues of fact exist regarding the particular purpose element of Mrs. Glynn's claim. Defendant argues that the particular purpose, if there is one, is

[5] Any citations to Drb7 mean Defendant's reply brief at page 7. Likewise, any citations to "Db" and a number or "Pb" and a number mean Defendant or Plaintiffs' brief at a page number.

the treatment and prevention of osteoporosis while Plaintiffs argue that the purpose was to treat osteoporosis and reduce fractures. In addition, it is unclear exactly what implied warranty, if any, Defendant communicated to the prescribing physicians. Because Defendant has not demonstrated the absence of a genuine issue of material fact and it is unclear whether it is entitled to judgment as a matter of law on this claim, this Court will deny summary judgment without prejudice.

C. Violations of New York General Business Law

In their Complaint, Plaintiffs allege that Defendant violated two sections of the New York General Business Law: § 349 and § 350. Defendant argues that summary judgment should be granted because (1) Plaintiffs cannot show reliance on any Fosamax advertising or marketing, meaning the § 350 claim fails; and (2) Plaintiffs § 349 claim is preempted by federal law.

Section 349 of the New York General Business Law provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful." N.Y. GEN. BUS. LAW § 349(a). Section 350 states "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful." N.Y. GEN. BUS. LAW § 350. "These statutes on their face apply to virtually all economic activity, and their application has been correspondingly broad." *Goldych v. Eli Lilly & Co.*, 2006 WL 2038436, *6 (N.D.N.Y. Jul. 19, 2006). The "elements for both of these causes of action are (i) that defendants engaged in conduct that was misleading in a material respect; (ii) the deceptive conduct was 'consumer oriented'; and (iii) that the plaintiff was injured *'by reason of'* defendant's conduct." *Id.* "[C]ompliance with FDA warning requirements is a complete defense" to both of these statutes.

Am. Home Products Corp. v. Johnson & Johnson, 672 F. Supp. 135, 144 (S.D.N.Y. 1987); *see also* N.Y. GEN. BUS. LAW §349(d) (providing "it shall be a complete defense that the act or practice is . . . subject to and complies with the rules and regulations of, and the statutes administered by, the federal trade commission or any official department, division, commission or agency of the United States"); N.Y. GEN. BUS. LAW §350-c (stating it shall be a complete defense if an individual presents "evidence that the advertisement is subject to and complies with the rules and regulations of, and the statutes administered by, the Federal Trade Commission"); *Am. Home Products Corp.*, 672 F. Supp. at 144 (recognizing that "New York courts have construed" § 350-c "to cover regulations by other federal agencies" as well as the Federal Trade Commission).

The Court will grant Defendant's Motion for Summary Judgment as to §§ 349 and 350. Fosamax is approved by the FDA, and therefore, this approval is a complete defense to a § 349 claim. *See Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998); *Am. Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987).

Regarding § 350, Plaintiffs cannot bring an action for false advertising because the parties have stipulated that "Mrs. Glynn does not claim to have seen any advertising for Fosamax." Final Pretrial Order, p. 3.

Because there is no genuine issue of material fact regarding these claims, Defendant is entitled to judgment as a matter of law, and its Motion for Summary Judgment is granted as to Plaintiffs' New York General Business Law claims.

D. Punitive Damages

The parties dispute the choice of law standard that applies to punitive damages. Plaintiffs argue that New York or Pennsylvania law applies while Defendant asserts that New Jersey law applies. This Court denies summary judgment because it needs a trial record to decide which states' law applies to punitive damages. The Motion may be renewed at the close of Plaintiffs' case.

III. CONCLUSION

For these reasons, the Court denies Defendant's Motion for Summary Judgment without prejudice as to failure to warn, breach of implied warranty of fitness for a particular purpose, and punitive damages and grants the Motion as to New York General Business Law §§ 349 and 350. An Order accompanies this Opinion.

Dated: April 11, 2013

/s/ Joel A. Pisano
JOEL A. PISANO
United States District Judge